

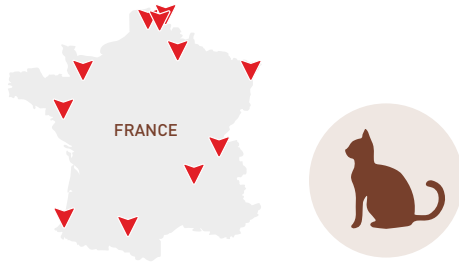
A study to evaluate the efficacy, digestive tolerance and palatability of ROYAL CANIN® GASTROINTESTINAL HYDROLYZED PROTEIN diet in cats with chronic enteropathies



VETERINARY CLINICS INVOLVED

The objective of this field study was to evaluate the performance of the new ROYAL CANIN® GASTROINTESTINAL HYDROLYZED PROTEIN feline dry veterinary diet in a practice setting.

The study took place in France; 11 companion animal veterinary clinics returned a total of 14 completed cases.



TRIAL PROTOCOL

SELECTION CRITERIA

INCLUSION

- Adult cats with a gastrointestinal disorder
- Dewormed and treated against external parasites (fleas, ticks, etc.)
- With an adapted Feline Chronic Enteropathy Activity Index Score (FCEAI) (without blood analysis) ≥ 3
- Chronic enteropathies: with soft or liquid stools at least twice a week for at least 2 weeks and one or more of the following signs: increased frequency of stools - increased stool volume - vomiting
- OR Recurrent enteropathies: with soft or liquid stools and one or more of the following signs: increased frequency of stools - increased stool volume - vomiting AND that already consulted for soft or liquid stools at least once within the past year, except if the gastrointestinal (GI) disorder was caused by the consumption of inappropriate elements by the pet, stress or concomitant known disease
- No current medication

Animals previously medicated under one or more protocols (anti-inflammatory, antibiotic) and did not fully respond to treatment were authorized.

EXCLUSION/WITHDRAWAL

- Severe concurrent disease
- Refusal to eat, insufficient food consumption (<80% ration over 3 days)
- Worsening of signs during trial
- Use of prohibited medications
- Undesired weight loss in excess of 15%

INTERVENTIONS

Dietary treatment only (= test diet only, no additional medication) was preferred, but some treatments were left at the vet's discretion to reflect real-life practice.

PROHIBITED MEDICATIONS:

- Short-term and long-acting (injectable or oral) steroids
- Essential fatty acid supplements, antibiotic treatments, parenteral/oral antiemetics after food transition

AUTHORIZED DURING THE STUDY, IF DEEMED NECESSARY BY THE VET:

- Interventions with no impact on GI tract: shampoos, ear cleansers, ear drops, external antiparasiticide application, etc.
- Vitamin B9 and B12 supplementation

POPULATION CHARACTERISTICS

DESCRIPTION OF COMPLETED CASES	
NUMBER	14
GENDER	8 Males (5 neutered, 3 intact) 6 Females (5 spayed, 1 intact)
AGE AT V0: MEAN (RANGE)	5.9 years (2-16 years)
BODYWEIGHT AT V0: MEAN (RANGE)	4.3 kg (2.1-7.2 kg)
BODY CONDITION AT V0	Thin to normal
BODY CONDITION SCORE (BCS) V0	2 [4(26%)]; 3 [1(7%)]; 4 [3(20%)]; 5 [1(7%)]; 6 [6(40%)]
FCEAI AT V0: MEAN (RANGE)	6.2 (3-11)

TRIAL PROTOCOL

STUDY DESIGN



ASSESSMENT OF THE EFFICACY OF THE DIET

BY THE VET (V0, VS1 AND VS2):

- Physical examination including cat's body weight and Body Condition Score (BCS)
- Gastrointestinal discomfort signs evaluation: presence or absence of diarrhea, vomiting, melena or hematochezia, fecal mucus, abdominal pain, tenesmus, abnormal behavior, or any other GI-related clinical signs
- Gastrointestinal Disorders Evaluation Scale (calculated from validated Feline Chronic Enteropathy Activity Index score (FCEAI))

BY THE CAT OWNER (V0, Phone Call, VS1, VS2):

- Scoring of digestive signs: appetite, vomiting/nausea, stool consistency, stool frequency, pain/discomfort
- Scoring of quality of life (QoL): score from 1 = very deteriorated to 10 = very good
- Scoring the owners' perspective of the impact of the animal's condition on their own routine. Score from 1 = not at all bothersome to 10 = extremely bothersome
- Scoring of interaction and play: score from 1 = very deteriorated to 10 = very good

- Inclusion visit (V0), at day 0: full clinical examination by the vet including blood sampling and completion of questionnaire
- Follow-up phone call (PC) at day 7: follow-up/ collection of owner inputs on signs evolution
- Follow-up vet visit at 1 month (VS1): follow-up/ collection of owner inputs on food consumption and vet clinical examination for any changes in clinical signs
- Final visit (VS2) at 2 months: same as VS1 + evaluation of product efficacy

FCEAI SCORE (WITHOUT BLOOD ANALYSIS)

CLINICAL SIGNS	SCORING
ATTITUDE / ACTIVITY	0 = normal 1 = slightly decreased 2 = moderately decreased 3 = severely decreased
APPETITE	0 = normal 1 = slightly decreased 2 = moderately decreased 3 = severely decreased
VOMITING	0 = normal, no vomiting 1 = mild vomiting (1x/week) 2 = moderate vomiting (2-3x/week) 3 = severe vomiting (>3x/week)
STOOL CONSISTENCY	0 = normal 1 = slightly soft feces 2 = very soft feces 3 = watery diarrhea
STOOL FREQUENCY	0 = normal 1 = slightly increased (2-3x/day) or fecal blood, mucus or both 2 = moderately increased (4-5x/day) 3 = severely increased (>5x/day)
WEIGHT LOSS	0 = none 1 = mild (<5%) 2 = moderate (5-10%) 3 = severe (>10%)

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TRIAL RESULT

VET ASSESSMENT

- ✓ **Gastrointestinal (GI) disorder:** All the cats decreased their score and 79% reduced in clinical index activity score by 75% or more after 2 months (Fig. 1 & 2).

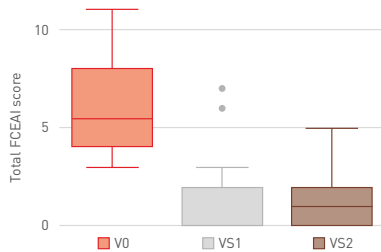


Fig. 1: Results from GI disorder evaluation scale (median and 25th and 75th percentiles)

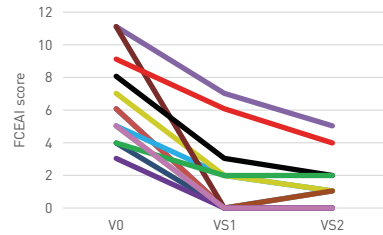


Fig. 2: Individual evolution of FCEAI score

- ✓ **Clinical signs:** Almost all the parameters of the FCEAI score improved for all cats. Normal score (0) was higher for all parameters at VS2 than V0 (Fig. 3).

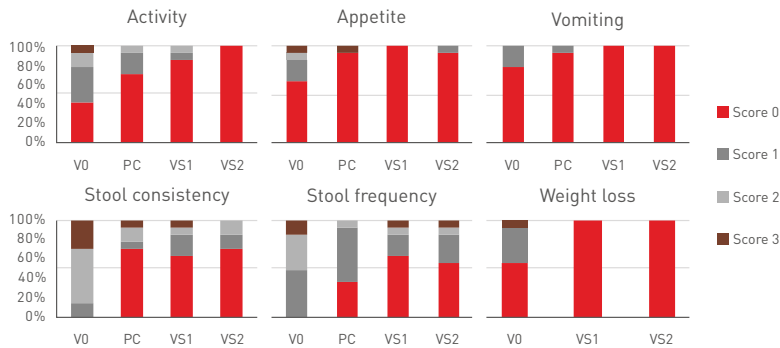


Fig. 3: Results of the main parameters of FCEAI score (percentage of cats presenting each score).

- ✓ **BW:** evolution from +2 to +41%.
- ✓ **Palatability:** All cats readily ate the diet during the study.

PET OWNER ASSESSMENT

- ✓ **GI signs:** improvement or resolution of GI signs were reported for all cats, except one, that completed the two month trial.

- ✓ **Quality of Life (QoL):** 93% of pet owners reported an improved QoL after 2 months (Fig. 4). Mean score from 5.4 at V0 to 9.1 at VS2.

- ✓ **Owners' viewpoint:** 79% of pet owners that completed the 2 month trial reported that the negative impact induced by their pet's condition on their daily life was reduced after the trial. (Fig. 5).

Mean score from 5.7 at V0 to 2.7 at VS2.

- ✓ **Interaction and play:** Improvement of interaction in 79% of cats and improvement of play in 57% of cats that completed the 2 month trial. Mean interaction score from 5.9 at V0 to 8.2 at VS2. Mean play score from 5.6 at V0 to 6.6 at VS2.

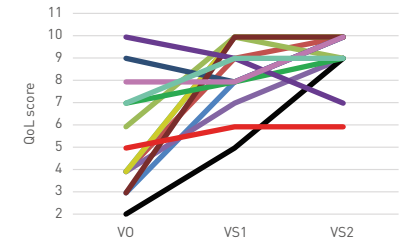


Fig. 4: Individual evolution of QoL (owner perception). QoL score decreases when QoL is altered.

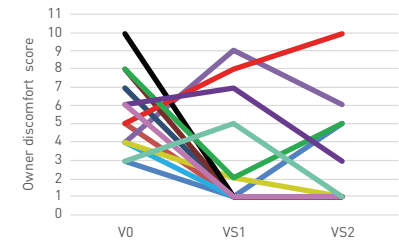


Fig. 5: Individual evolution of owners' viewpoint. Owners' viewpoint on discomfort score increases when altered.

ADDITIONAL RESULTS

- ✓ **Vet satisfaction & diet efficacy:** 100% of vets with patients involved in this study were satisfied with the diets.
- ✓ **Pet owner satisfaction & intention to repurchase:** Pet owner satisfaction with the diet was rated good to excellent in 100% of cats. 100% of pet owners said that they would purchase the diets if commercially available.